

Applicant: Townsend et al.  
USSN 09/877,987  
Filed: June 8, 2001  
Dkt: D009NP;30436.53USU1  
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REMARKS

The amendments to claims 11, 28 and 36 merely correct the dependency of the claims.

Accordingly, the changes do not involve new matter and entry of the changes is respectfully requested.

RESTRICTION REQUIREMENT

In the Office Action dated October 3, 2002, the Examiner is requiring restriction under 35 USC §121 to one of the following allegedly independent and distinct inventions:

Group I: claims 1-18 which are directed to methods of inhibiting or regulating immune responses with three agents, classified in Class 424, subclass 130.1 and Class 514, subclasses 8 and 885.

Group II: claims 19-35 which are directed to compositions and kits comprising three agents, classified in Class 424, subclass 130.1, Class 435, subclass 810 and Class 514, subclass 8 and 885.

Claim 36 was not relegated into either Group I or II.

ELECTION WITH TRAVERSAL

Applicants hereby elect the invention of Group I, with traverse, for prosecution at this time.

Applicants respectfully traverse the restriction requirement for the following reasons:

Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under MPEP §803, the Examiner must examine the application on the merits, even

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though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely, 1) the invention must be independent or distinct, and 2) there must be a serious burden on the Examiner if restriction is not required.

The inventions recited in the claims of Groups I and II are directed to a combination of three agents for regulating immune responses and uses thereof.

No undue burden for the Examiner

Applicants further maintain that there would not be a serious burden on the Examiner if restriction is not required for the claims of Groups I-II. The claims in Groups I and II are both classified in Class 424, subclass 130.1 and Class 514, subclass 8, 885. Thus, a search of prior art with regard to the claims of Group I will reveal whether any prior art exist for the claims of Group II. Separate prosecution of these claims would be unnecessarily duplicative and thus wasteful of Patent Office resources. Therefore, under MPEP Section 803, the instant claims do not require restriction of Groups I-II.

SPECIES RESTRICTIONS

The Examiner requires species election for the claims of Group I/II. In response, Applicants hereby elect, with traverse, the invention of Group I wherein the species of agent 1 is soluble CTLA4, the species of agent 2 is anti-CD154 monoclonal antibodies and the species of agent 3 is anti-LFA-1 monoclonal antibodies. Claims that read upon the elected species are claims 1-9, 11-26, 28-34 and 36.

Applicant respectfully requests that the Examiner reconsiders and withdraws the species election requirement.

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**FORMAL DRAWINGS**

The Office has indicated that Figures 2-13 are not in compliance with 37 CFR §1.84.

Applicants provide herein substitute Figures 1-13 (Exhibit 1), which comply with 37 CFR §1.84.  
Substitute Figures 1-13 contain no new matter and their entry is respectfully requested.

No fee, other than the filing fee, is deemed necessary in connection with the filing of this Amendment. If any additional fee is necessary, the Patent Office is authorized to charge the additional fee to Deposit Account No. 50-0306.

Respectfully submitted,

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**MARKED UP VERSION OF AMENDED CLAIMS**

- 11. (amended) The method of claim 9 [10], wherein the anti-LFA-1 monoclonal antibody is ATCC HB-9579 or ATCC TIB-213; wherein the anti-ICAM-1 monoclonal antibody is ATCC CRL-1878 or ATCC HB-233; wherein the anti-CD11a monoclonal antibody is M17/5.2 (ATCC TIB-237), ATCC HB-202, ATCC HB-244 or ATCC TIB-217; wherein the anti-CD18 monoclonal antibody is ATCC HB-203, ATCC HB-226 or ATCC TIB-218; and wherein the anti- $\alpha$ -actinin monoclonal antibody is ATCC CRL-2252.--
- 28. (amended) The pharmaceutical composition of claim 26 [27], wherein the anti-LFA-1 monoclonal antibody is ATCC HB-9579 or ATCC TIB-213; wherein the anti-ICAM-1 monoclonal antibody is ATCC CRL-1878 or ATCC HB-233; wherein the anti-CD11a monoclonal antibody is M17/5.2 (ATCC TIB-237), ATCC HB-202, ATCC HB-244 or ATCC TIB-217; wherein the anti-CD18 monoclonal antibody is ATCC HB-203, ATCC HB-226 or ATCC TIB-218; and wherein the anti- $\alpha$ -actinin monoclonal antibody is ATCC CRL-2252.—
- 36. (amended) The kit of claim 34 [35], wherein the anti-LFA-1 monoclonal antibody is ATCC HB-9579 or ATCC TIB-213; wherein the anti-ICAM-1 monoclonal antibody is ATCC CRL-1878 or ATCC HB-233; wherein the anti-CD11a monoclonal antibody is M17/5.2 (ATCC TIB-237), ATCC HB-202, ATCC HB-244 or ATCC TIB-217; wherein the anti-CD18 monoclonal antibody is ATCC HB-203, ATCC HB-226 or ATCC TIB-218; and wherein the anti- $\alpha$ -actinin monoclonal antibody is ATCC CRL-2252.—